Abstract

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Title of thesis: Evaluation of the chosen active substance in the preparation by UHPLC II.

Method for the determination of sodium picosulfate monohydrate, its related substances and sodium benzoate using ultra high performance liquid chromatography (UHPLC) was validated. This method has been transmitted from the conditions of previously validated and optimized high performance liquid chromatography (HPLC) method. Separation of the substance was achieved with Kinetex® 2.6 micron C18, 100A, 150 x 3.00 mm, 2.6 microns column using UV detection at a wavelength of 263 nm. The mobile phase consisted of buffer, acetonitrile and propan-2-ol in a ratio of 55: 43: 2 (v/ v/v). The buffer contained sodium dihydrogen phosphate, cetyltrimethylammonium bromide and water. The pH 7.0 of the buffer was achieved by phosphoric acid. The column temperature was 40 ° C, injection volume 3 µl, the flow rate was set at 0.5 ml/min.

The method was evaluated as sufficiently selective, precise, exact, linear and sensitive. Furthermore robustness was tested according to the Plackett-Burman design. It was found, that the acetonitrile volume in the mobile phase has the most significant infuence on the performance of separation. The separation was less affected by pH, flow and quantity of cetyltrimethylammonium bromide.